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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ONE HEALTH PLAZA 430/2
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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,498	WELSH ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-62 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1 consists of $4.5x10^{105}$ inventions.

Claims 1-10 are drawn to a method for screening a subject for a prostate disorder comprising screening for at least one gene identified in Tables 2, 3, or 4, classified in Class 435, subclass 4, 6, 7.1. It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is $73!= 4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be analyzed. Claim 3 will be examined as it is drawn to the elected invention.

Group 2 consists of $4.5x10^{105}$ inventions.

Claims 1-10 are drawn to a method for screening a subject for risk of developing a prostate disorder comprising screening for at least one gene identified in Tables 2, 3 or 4 classified in Class 435, subclass 4, 6, 7.1. . It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is $73!= 4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be analyzed. Claim 3 will be examined as it is drawn to the elected invention.

Group 3 consists of $4.5x10^{105}$ inventions.

Claims 11-20 are drawn to a method for monitoring the progression of a prostate disorder for at least one gene identified in Tables 2, 3 or 4, classified in Class 435, subclass 4, 6, 7.1. It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is 73!= $4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be analyzed. Claim 13 will be examined as it is drawn to the elected invention.

Group 4 consists of $4.5x10^{105}$ inventions.

Claims 11-20 are drawn to a method for monitoring the progression of a subject for risk of developing a prostate disorder for at least one gene identified in Tables 2, 3 or 4, classified in Class 435, subclass 4, 6, 7.1. It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is 73!= $4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be analyzed. Claim 13 will be examined as it is drawn to the elected invention.

Group 5 consists of $4.5x10^{105}$ inventions.

Claims 21-31 are drawn to a method for identifying agents for use in the treatment of a prostate disorder of a prostate disorder comprising detecting a level of expression of at least one gene from Tables 2, 3, 4, classified in Class 435, subclass 4, 6, 7.1. It is noted that it appears that Tables 2,3 and 4 consist of

73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is $73!= 4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be analyzed. Claim 23 will be examined as it is drawn to the elected invention.

Group 6 consists of $4.5x10^{105}$ inventions.

Claims 32-43 are drawn to a method for inhibiting undesired proliferation of a prostate cell comprising administering an agent that can decrease the expression of at least one gene from Tables 2, 3, 4, classified in Class 424, subclass 130.1, Class 514, subclass 2+ and Class 536, subclass 23.1. . It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is $73!= 4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be targeted. Claim 36 will be examined as it is drawn to the elected invention.

Group 7 consists of $4.5x10^{105}$ inventions.

Group 7. Claims 44-53 are drawn to a method for monitoring the efficacy of a treatment of a patient of a patient with a prostate disorder comprising administering an agent that can decrease the expression of at least one gene from Tables 2, 3, 4, classified in Class 435, subclass 4, 6, 7.1. . It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of

combinations claimed is 73!= $4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be assayed. Claim 46 will be examined as it is drawn to the elected invention.

Group 8 consists of $4.5x10^{105}$ inventions.

Claims 44-53 are drawn to a method for monitoring the efficacy of a treatment of a patient at for risk of developing a prostate disorder comprising administering an agent that can decrease the expression of at least one gene from Tables 2, 3, 4, classified in Class 435, subclass 4, 6, 7.1. It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations claimed is 73!= $4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single gene product or a specific combination of gene products to be assayed. Claim 46 will be examined as it is drawn to the elected invention.

Group 9 consists of $4.5x10^{105}$ inventions.

Claims 54-57 are drawn to viral vectors comprising a promoter and/or enhancer of at least one gene of the apparent 73 genes of Tables 2, 3 and 4, classified in Class 435, subclass 91.4. It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes and thus 73 different sets of promoter and/or enhancers. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations of vectors comprising a promoter and/or enhancer of at least one gene claimed is 73!= $4.5x10^{105}$. It is noted for Applicant's

convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single promoter and/or enhancer of a single gene or a specific combination of said promoter and/or enhancers for examination.

Group 10 consists of $4.5x10^{105}$ inventions.

Claims 58-62 are drawn a nucleic acid construct comprising comprising a promoter and/or enhancer of at least one gene of the apparent 73 genes of Tables 2, 3 and 4 and a heterologous gene product, classified in Class 435, subclass 91.4. It is noted that it appears that Tables 2,3 and 4 consist of 73 distinct genes and thus 73 different sets of promoter and/or enhancers. It is further noted that by factorial analysis, n!=number of combinations, the number of combinations of promoter and/or enhancer of at least one gene claimed is $73!= 4.5x10^{105}$. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single promoter and/or enhancer of a single gene or a specific combination of said promoter and/or enhancers for examination.

3. It is noted that claim 1 of Group 1 is a linking claim.

Claim 1, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the

claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

For each of the inventions of Group 1, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 1 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 1 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 1, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 1-10 will be examined as they are drawn to the specifically elected invention.

4. It is noted that claim 1 of Group 2 is a linking claim.

Claim 1, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

For each of the inventions of Group 2, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 2 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 2 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 2, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 1-10 will be examined as they are drawn to the specifically elected invention.

5. It is noted that claim 11 of Group 3 is a linking claim.

Claim 11, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

For each of the inventions of Group 3, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 3 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 3 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 3, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 11-20 will be examined as they are drawn to the specifically elected invention.

6. It is noted that claim 11 of Group 4 is a linking claim.

Claim 11, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the

instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

For each of the inventions of Group 4, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 4 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 4 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 4, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 11-20 will be examined as they are drawn to the specifically elected invention.

7. It is noted that claim 21 of Group 5 is a linking claim.

Claim 21, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 21. Upon the allowance of the linking claim(s), the restriction requirement as to the

linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

For each of the inventions of Group 5, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 5 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 5 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 5, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 21-31 will be examined as they are drawn to the specifically elected invention.

8. It is noted that claim 32 of Group 6 is a linking claim.

Claim 32, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 32. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

For each of the inventions of Group 6, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 6 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 6 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species

requirement in that each of the linked groups consists of one of the inventions of Group 6, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 32-43 will be examined as they are drawn to the specifically elected invention.

9. It is noted that claim 44 of Group 7 is a linking claim.

Claim 44, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

For each of the inventions of Group 7, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 7 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 7 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 7, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 44-53 will be examined as they are drawn to the specifically elected invention.

10. It is noted that claim 44 of Group 8 is a linking claim.

Claim 44, links inventions (A-B)(i-v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if

any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

For each of the inventions of Group 8, restriction to one of the following is also required under 35 USC121.

(A) detection by assaying for expression of mRNA

(B) detection by assaying for expression of protein.

For each of the inventions of Group 8 and (A)-(B) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of the inventions of Group 8 **and** one of inventions (A)-(B) **and** one of inventions (i)-(v) below. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 8, **and** one of inventions (A)-(B) above **and** one of inventions (i)-(v) below.

(i) localized prostate cancer

(ii) metastasized prostate cancer

(iii) prostatitis

(iv) benign prostatic hypertrophy

(v) benign prostatic hyperplasia

Claims 44-53 will be examined as they are drawn to the specifically elected invention.

11. It is noted that claim 58 of Group 10 is a linking claim.

Claim 58, links inventions (A-E). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

For each of the inventions of Group 10, restriction to one of the following is also required under 35 USC121.

(A) the heterologous gene product is an RNA molecule

(B) the heterologous gene product is an antisense RNA

(C) the heterologous gene product is a ribozyme

(D) the heterologous gene product is a protein

(E) the heterologous gene product is a cytokine

(F) the heterologous gene product is a toxin.

Election is required of one of the inventions of Group 10 **and** one of inventions (A)-(F). It is noted that this is not an election of species requirement in

that each of the linked groups consists of one of the inventions of Group 9, **and** one of inventions (A)-(F).

Claims 58-62 will be examined as they are drawn to the specifically elected invention.

12. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 9-10 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions of Groups 1-8 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1-8 and 9-10 do not appear to be at all related because it does not appear that either the viral vector of the nucleic acid construct comprising a promotor and/or enhancer of at least one gene of the apparent 73 genes of Tables 2, 3 and 4 and a heterologous gene product are used in any of the methods of Groups 1-8.

Further, the inventions of Groups 1-10 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP . 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself

because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar, PhD
Primary Patent Examiner
September 14, 2004